K070528

5 510(k) Summary

In accordance with the requirements of 21 CFR 807.92

1. **Submitted by**
Philips Medical Systems
22100 Bothell Everett Highway
Bothell, Washington 98021-8431
Establishment Registration No. 1217116
Contact: Lynn Hamer
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Date prepared: January 31, 2007

MAR 0 9 2007

2. **Manufacturer:**
Philips Medical Systems DMC GmbH
Roentgenstrasse24
Hamburg, Germany D-22335
Establishment Registration No. 3003768251

3. **Device name and classification**
Trade name: *Essenta DR*
Classification name: *Stationary X-ray system and Solid State X-ray Imager*
Classification panel: *Radiology devices*
Regulatory status: *Class II*
Device classification reg. nr.: *21CFR 892.1680 and 21 CFR 892.1650*

4. **Predicate device**
Trade name: *PHILIPS BUCKY VISION*
Manufacturer: *PHILIPS MEDICAL SYSTEMS*
K-Number: *K982795*

5. **Description**
The *Essenta DR* is a multifunctional system, in which a swivel arm holds the x-ray tube and the x-ray detector. The generator, x-ray tube housing assembly, beam limiting device, detector, including the workstation for image processing and the optional mobile x-ray table (trolley) are known components. The geometry of the *Essenta DR* contains a central column, on which the height-adjustable and rotatable swivel arm is mounted. The rotatable detector and the rotatable x-ray tube with control section are mounted at the swivel arm. This enables the radiation beam to be adjusted to any position on a vertical plane. A second control section on the detector carrier allows positioning on the patient to be carried out at the detector itself. The vertical adjustment of the swivel arm, the rotation of the swivel arm and the SID adjustment are motorized. It enables the operator to quickly and safely move the unit to all the pre-programmed basic positions at the press of a button, using the auto-positioning feature. Fine positioning of the tube/collimator and detector on the patient is easy to carry out using the command arm.

6. **Intended Use**
   The *Essenta DR* is a digital multifunctional X-ray system, suitable for all routine radiographic exams, including specialist areas like trauma or pediatric work, excluding mammography. It is designed for radiographic examination of the standing or seated patient or the recumbent patient in combination with a mobile x-ray table (trollcy). The system is intended for direct digital imaging using the built in flat panel detector and in addition for free exposures on radiographic cassettes.
7. **Comparison to predicate device**
   The *Essenta DR* does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the *Essenta DR* to be substantially equivalent with the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Phillips Medical Systems
% Mr. Marc M. Mouser
Senior Project Engineer/Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

AUG 23 2013

Re: K070528
Trade/Device Name: *Essenta DR*
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB and IZL
Dated: February 22, 2007
Received: February 23, 2007

Dear Mr. Mouser:

This letter corrects our substantially equivalent letter of March 9, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070528

Device Name: *Essenta DR*

Indications For Use:

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It is designed for radiographic examination of the standing or seated patient or the recumbent patient in combination with a mobile x-ray table (trolley).

The system is intended for direct digital imaging using the built in flat panel detector and in addition for free exposures on radiographic cassettes.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070528